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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,063	09/10/2003	Mitchell P. Fink	UPITT-008XX	3827
207	7590	06/12/2006		EXAMINER
WEINGARTEN, SCHURGIN, GAGNEBIN & LEOVICI LLP			HENRY, MICHAEL C	
TEN POST OFFICE SQUARE			ART UNIT	PAPER NUMBER
BOSTON, MA 02109			1623	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,063	FINK ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 March 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6, 8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 03/06/06.

The amendment filed 03/06/06 affects the application, 10/659,063 as follows:

Claims 1-6 and 8, the invention of Group I are prosecuted by the examiner.

Claims 9-13 are withdrawn. Claim 7 has been canceled. Applicant's arguments, see Remarks, pages 5-7, filed 03/06/06, with respect to claims 1-6 and 8 have been fully considered and are not persuasive. Consequently, the rejection of the prior office action is maintained.

The responsive to applicants' arguments is contained herein below.

Claims 1-6, 8-13 are pending in application

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Lund et al. (US 2002/0127646 A1)

In claim 1, the applicant claims "A method for treating of an inflammatory condition, said method comprising the steps of: providing a patient having an inflammatory condition; and administering to said patient a therapeutically effective amount of a composition comprising cyclic adenosine diphosphate ribose (cADPR), or a functional analogue or derivative thereof, in a form that is accessible to a receptor molecule, conveyed in a pharmaceutically acceptable carrier vehicle, wherein said composition reduces the degree of said inflammatory condition in

said patient.” Claims 2-6 and 8 are drawn to said method involving specific inflammatory conditions, specific routes of administration and the use of specific functional analogs and derivative of cADPR.

Lund et al. disclose that modulators, such as agonists and antagonists, of CD38 enzyme activity and/or modulators of cADPR dependent calcium responses and chemotaxis can be used in the treatment of disorders including inflammation in a subject (see page 4, 2nd col. paragraph [0032]). Furthermore, Lund et al. disclose examples of said antagonists (modulators) of cADPR which are cADPR derivatives and include, 8-NH₂-cADPR, 8-Br-cADPR, 8-CH₃-cADPR, 8-OCH₃-cADPR and 7-Deaza-8-Br-cADPR (see page 11, 1st col., paragraph [0099]).

The difference between applicant’s claimed method and the method disclosed by Lund et al. is that Lund et al. do not exemplify the use of a cADPR derivative to treat inflammation in a subject. However, Lund et al. teach that antagonists (modulators) of cADPR such as a cAPDR derivative can be used to treat inflammation in a subject (see page 4, 2nd col. paragraph [0032] and see page 11, 1st col., paragraph [0099]).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Lund et al. to treat inflammation in a subject by administering to said subject a cADPR derivative, based on need, since Lund et al. teach that antagonists (modulators) of cADPR such as a cAPDR derivatives can be used to treat inflammation in a subject.

One having ordinary skill in the art would have been motivated in view of Lund et al. to treat inflammation in a subject by administering to said subject a cADPR derivative, based on need, since Lund et al. teach that antagonists (modulators) of cADPR such as cAPDR derivatives

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can be used to treat inflammation in a subject. It should be noted that the administration via specific routes is common and obvious in the art and it is obvious to use any derivative, since Lund et al. disclose that cAPDR derivatives can be used.

Response to Amendment

Applicant's arguments with respect to claims 1-6 and 8 have been considered but are not found convincing.

The applicant argues that "the active compound in the Applicants' method of treating an inflammatory condition is cADPR itself or an analogue having the same function. In other words, the Applicants' method requires an agonist of cADPR activity." However, applicant's claim is drawn to treating an inflammatory condition with a derivative of cADPR and does not recite or states any limitation that requires the said cADPR derivative to be an agonist (see claim 1).

The applicant argues that "The specification of the patent application of von Lund et al., however, teaches a different effect in that Lund et al. teaches that antagonists (modulators) of cADPR such as a cADPR derivative can be used to treat: inflammation in a subject" (emphasis added), the exact opposite of the treatment the Applicants are claiming. However, applicant's method (as claimed) is drawn to the uses cADPR derivatives (in general) to treat inflammation and does not exclude the use of cADPR derivatives that are antagonist (see claim 1).

The applicant argues that Lund et al. teaches the exact opposite treatment to the Applicants' claimed method for the exact opposite condition, the Applicants submit that Lund et al. is a clear teaching away situation and that one of ordinary skill would never have been led to the Applicants' invention through any of the Lund et al. teachings. However, Lund et al., like

the applicant, teach that cADPR derivatives can be used to treat inflammation (which equates to the same effect) and consequently one of ordinary skill would have been led to the Applicants' invention through Lund et al. teachings. Moreover, it should be noted that Lund et al. disclose that modulators, such as agonists and antagonists, of CD38 enzyme activity and/or modulators of cADPR dependent calcium responses and chemotaxis can be used in the treatment of disorders including inflammation in a subject (see page 4, 2nd col. paragraph [0032]). This implies that the modulators can be agonist and antagonist such as the cADPR derivatives disclosed by Lund et al. (see page 11, cols. 1-2, paragraph [0099]).

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652.

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The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang, Ph.D can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

Michael C. Henry



Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

June 6, 2006.